

REMARKS

Status of the Claims

Claims 1 – 226 are pending. Claims 40 – 111 have been withdrawn from consideration.

Claim Amendments

The amendment to claim 19 does not add new matter, because the amendment merely corrects a typographical error. Support for the amendment can be found throughout the specification, for example in paragraph [0024] of the published application (US 20050214892 A1). Entry of the amendment to claim 19 would not require further examination or search.

Objections to the Claims

The objection to claim 19 is moot in view of the amendment.

Claim Rejections

- I. The Office action rejects claims 1 – 18, 135 – 154, and 195 – 214, citing 35 U.S.C §101.

“A claimed process is surely patent-eligible under §101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *In re Bilski* 545 F. 3d 943 at 954 (Fed.Cir.2008), citing *Gottschalk v. Benson*, 409 U.S. 63, 70, 93 S.Ct. 253, 34 L.Ed.2d 273 (1972) (emphasis added). The Office action errs by requiring the present invention to be tied to a particular machine and to transform a particular article into a different state or thing. Regarding (1) the Federal Circuit left “to future cases the elaboration of the precise contours of machine implementation, as well as the answers to particular questions, such as whether or when recitation of a computer suffices to tie a process claim to a particular machine.” *In re Bilski* 545 F. 3d at 962. Regarding (2), the Court cited the case of *Abele, Meyer, Grams, Arrhythmia Research Technology, Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed.Cir.1992) to provide an example of which processes qualify as a transformation or reduction of an

article into a different state or thing constituting patent-eligible subject matter. More specifically, the court explained one of Abele's dependent claims was drawn to patent-eligible subject matter. The dependent claim specified, "said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner." The Federal Circuit did not add a requirement that the data transformed into a different state or thing be obtained by a particular machine. Instead, the Court made clear "[t]his data clearly represented physical and tangible objects, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that ... process patent-eligible. [The Court] further note[d] for clarity that the electronic transformation of the data itself into a visual depiction in *Abele* was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented." *In re Bilski* 545 F. 3d at 963.

The data transformed according to the presently claimed invention clearly represents physical and tangible objects, namely the glycosylated hemoglobin level of a patient. Therefore, applicants respectfully submit the "claimed process is surely patent-eligible under §101 [because] it transforms a particular article into a different state or thing." *In re Bilski* 545 F. 3d at 954. Favorable reconsideration and withdrawal of the rejection is respectfully requested.

II. The Office action rejects claims 1 – 18, 135 – 154, and 195 – 215, citing 35 U.S.C. §112, first paragraph.

Support for the recitation of "electronically transforming the estimate into a visual depiction" and "outputting the visual depiction of the estimate to a user," in claims 1 – 18, 135 – 154, and 195 – 215 can be found throughout the specification and in the claims as originally filed, for example, but not limitation, in paragraphs [0047], [0093], [0108], [0109], [0113], [0116], [0372], [0485], [0498], [0509] of the published application. Since the claimed subject matter was described in the specification so as to convey to a person having ordinary skill in the art that applicants had possession of the invention at the time the application was filed, favorable reconsideration, and withdrawal of the rejection is respectfully requested.

III. The Office action rejects claims 1 – 39 and 112 – 226, citing 35 U.S.C. §112, second paragraph.

MPEP § 2173.02, explains, “[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.”

Among other explanatory details, the published application includes paragraph [0325], which explains:

Special software was developed for pre-processing of the data. This included: (1) Assembling of the memory meter data for each subject into a continuous 6-8-month sequence of BG readings, and (2) Matching of each subject's records of SH with this sequence by date and time. The latter was performed as follows: for each SMBG reading the time (hours/minutes) until the nearest SH episode, and the time elapsed from the latest SH episode, were computed. Thus, it was possible to: (1) time 24-hour, 48-hour, etc. periods backward and forward from each SH episode, and (2) time periods between SMBG readings. Due to the nature of SH (stupor, unconsciousness), no SMBG was performed exactly at the time of SH, thus SH episodes for the purposed of Algorithm 3 do not include biochemical significant hypoglycemia that was used for Algorithm 2. The average per SH episode minimum elapsed time between SH and the nearest preceding SMBG reading was 5.2+-.4.1 hours; 29 SH episodes (7%) were preceded by a SMBG reading within 15 minutes. For each SH episode, we counted how many SMBG readings were performed within 24 h, 36 h, 48 h, and 72 h prior to that episode.

A person having ordinary skill in the art would interpret the claim to require a pre-processing of collected BG data, i.e., data that can be obtained, for example, but not limitation, from a patient. After pre-processing, the BG data is simply referred to as “derived BG data.”

In view of the disclosure, and the interpretation of a person having ordinary skill in the art, the claim meets the threshold requirements of clarity and precision. Favorable reconsideration and withdrawal of the rejection is respectfully requested.

Fee Authorization

The Director is hereby authorized to charge any deficiency in fees filed, asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account 14-1437. Please credit any excess fees to such account.

Conclusion

The present application is in condition for allowance, and applicants respectfully request favorable action. In order to facilitate the resolution of any questions, the Examiner is welcome to contact the undersigned by phone.

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